ONC Cures Act Final Rule and Interim Final Rule
What your organization needs to know

December 18, 2020 - In March 2020, the U.S. Department of Health and Human Services' (HHS) Office of the National Coordinator for Health IT (ONC) released the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule with the goal of increasing interoperability and patient access to electronic health information (EHI). The rule introduced the United States Core Data for Interoperability (USCDI v1) as the standardized set of health data classes and elements for health information exchange.

Background

The 21st Century Cures Act Final Rule introduced the new and modified 2015 Edition Health IT Certification Criteria, which certified Health IT developers must adopt over the next few years. The rule also implements information blocking requirements that ALL healthcare providers, certified Health IT developers, and health information exchanges (HIE) or health information networks (HIN) must comply with beginning **April 5, 2021***.

*On October 29, 2020, ONC released an interim final rule with a comment period. This rule extends the compliance dates and time frames mandated initially in the 21st Century Cures Act Final Rule.

USCDI

The ONC Cures Act final rule adopted the United States Core Data for Interoperability (USCDI v1) as the standardized set of health data classes and elements for health information exchange. This change impacts both health IT developer certification and information blocking legislation.

Health IT Developer Certification Requirements

As part of the 2015 Edition Cures Update, the USCDI will replace the Common Clinical Data Set (CCDS) — the data elements currently included in the Continuity of Care Document (CCD) and FHIR API.

Certified health IT developers must complete certification of products that include the USCDI v1 data elements by **December 31, 2022**. The USCDI includes all of the data elements within the CCDS, with the addition of several new data elements. More information on MEDITECH's certification plans and code delivery is discussed below in the "Certification Plans & Timelines" section.

Information Blocking

Information blocking is a practice by an actor (healthcare provider, health IT developer, health information exchange, or health information network) that — except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity — is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI). ONC includes eight information blocking exceptions designed to give actors flexibility while still maintaining privacy and security. Customers should refer questions regarding information blocking to their own organization's legal and compliance office.

Note: This information is based on what we know today and is subject to change.

Based on correspondence with ONC:

- Effective **April 5, 2021**, an actor must respond to a request for access, exchange, or use of EHI, with, at a minimum, the EHI requested _that they have_, that corresponds to any of the data elements represented in the USCDI. For instance, a healthcare provider who treats only older adults may be unlikely to have their patients' pediatric vital signs, so they would not be required to share pediatric vital signs.

- ONC also confirmed that the content of an actor's response is the EHI represented by the data elements in the USCDI, _not necessarily whether the actor is using the specific USCDI standard adopted for certification_ (i.e., CCD or API) to enable the access, exchange, or use. In other words, alternative communication methods are allowed to provide the requested information.

The methods of sharing EHI using MEDITECH functionality are outlined below.

Current Methods for Sharing Electronic Health Information
Continuity of Care Document (CCD) and FHIR API
Organizations with MEDITECH's 2015 certified EHR technology, including MEDITECH's 2015 Edition Continuity of Care (CCD) Interface Suite and FHIR API, can exchange the following USCDI data elements:

- Patient Name
- Current Address
- Phone Number(s)
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Smoking Status
- Problems
- Medications
- Medication Allergies
- Laboratory Tests and Laboratory Values / Result
- Vital Signs (Diastolic Blood Pressure, Systolic Blood Pressure, Body Height, Body Weight, Heart Rate, Respiratory Rate, Body Temperature, Pulse Oximetry, Inhaled Oxygen Concentration)
- Procedures
- Care Team Members
- Immunizations
- Unique Device Identifier *
- Assessment and Plan of Treatment *
- Goals *
- Health Concerns *

* Note: Organizations that do not have 2015 Edition CEHRT may not have the standard code required to capture these data elements on the CCD. Questions - contact your HCIS Coordinator/Account Manager.

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Data elements in new USCDI but **NOT** in 2015 certified CCD:

- Clinical Notes (Consultation Note, Discharge Summary Note, History & Physical, Imaging Narrative, Laboratory Report Narrative, Pathology Report Narrative, Procedure Note, Progress Note)
- Additional Demographic Data (Previous Address, Previous Name, Phone Number type, Email Address)
- Provenance (Author Time Stamp, Author Organization)
- Additional Vital Signs Information [BMI Percentile (2-20 years), Weight-for-length Percentile (Birth-36 Months), Head Occipital-frontal Circumference (Birth-36 Months)]

Alternative formats to provide all or augment information in the CCD with data that exists in current EHR (you only need to share data you have):

1. ***Patient Portal***

The following EHI is available on the portal for the acute care setting:
- CCD (Health Summary page)
- Demographic data including email and phone number type (Profile page)
- Clinical notes can be made available to view and download as a PDF file (Reports page).
- Pediatric vital sign information can be recalled into a Physician Documentation template to be sent to the Portal as part of an ITS/IDM report (Reports page).

The following EHI is available on the portal for the ambulatory care setting:
- CCD (Health Summary page)
- Demographic data including email and phone number type (Profile page).

2. ***Release of Information (ROI)***

For acute organizations with MEDITECH Scanning and Archiving (SCA), the ROI/eChart Output routine enables users to download a patient's archived medical record to a zip file, which is both machine and human-readable.

For a crosswalk of the methods for EHI sharing, please review the following:
- [Acute](#)
- [Ambulatory](#)

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Certification Plans & Timelines

MEDITECH is committed to meeting the developer certification requirements and associated dates. Dates for hospital/provider adoption have been finalized in the PFS/QPP Final Rule. For the full year in CY 2022, CMS has finalized that health care providers may use health IT certified to the existing 2015 Edition certification criteria, certified health IT updated to the 2015 Edition Cures Update, or a combination of updated and not-yet updated health IT modules. After December 31, 2022, a MIPS eligible clinician must demonstrate meaningful use of technology that meets the 2015 Edition Cures Update during the performance period.

MEDITECH is updating the CCD and releasing a new R4 FHIR API to add the data elements introduced with the USCDI; those data items are listed below:

- Clinical Notes (Consultation Note, Discharge Summary Note, History & Physical, Imaging Narrative, Laboratory Report Narrative, Pathology Report Narrative, Procedure Note, Progress Note)
- Additional Demographic Data (Previous Address, Previous Name, Phone Number type, Email Address)
- Provenance (Author Time Stamp, Author Organization)
- Additional Vital Signs Information [BMI Percentile (2-20 years), Weight-for-length Percentile (Birth-36 Months), Head Occipital-frontal Circumference (Birth-36 Months)]

MEDITECH anticipates USCDI-related code changes to be available for delivery in Q2 2021.

We are currently evaluating storage requirements for the file library as well as REST and/or compute resources for additional infrastructure required for this functionality. Additional information will be communicated once it is available.

Resources

- MEDITECH 21st Century Cures Act Resource Center
- USCDI Setup Guide (*Coming Soon*)
- USCDI Crosswalk (Acute)
- USCDI Crosswalk (Ambulatory)
- 2015 Edition CCD Supporting Documentation (Expanse/6.15, 6.08, C/S, MG)

Questions

Contact MEDITECH's Regulatory Mailbox.

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